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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,045	09/04/2003	Eugene Tedeschi	P297CON2(14364.108)	1082
28390	7590	11/04/2004		
MEDTRONIC VASCULAR, INC. IP LEGAL DEPARTMENT 3576 UNOCAL PLACE SANTA ROSA, CA 95403				
EXAMINER FUBARA, BLESSING M				
ART UNIT		PAPER NUMBER		
1615				

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/657,045	Applicant(s) TEDESCHI ET AL	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>08/16/04 & 05/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 05/20/04 and 08/16/04, amendment (to the claims and the specification) and remarks filed 08/16/04. New claims 16-25 are pending.

Information Disclosure Statement

The information disclosure statements filed 05/20/04 and 08/16/04 are received and the Form PTO-1449 is appropriately initialed.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1 and 3 under 35 U.S.C. 112, first paragraph is withdrawn because claim 1 and 3 are cancelled.

Double Patenting

2. The rejection of claims 1-15 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15 of prior U.S. Patent No. 6,379,691 is withdrawn in light of the cancellation of claims 1-15.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dinh et al. (US 5,554,182).

The claims are directed to stent (medical device) that is coated with polyurea or polyurethane polymer network. The coating composition comprises active agent such as

nitric oxide. The coating composition further comprises polysaccharide such as heparin.

The coated stent has utility is treating or inhibiting restenosis. The amount of the active agent decreases inwardly according to an inwardly decreasing gradient.

Dinh discloses an intraluminal stent that comprises a coating of fibrin and heparin for the treatment of restenosis; the fibrin can also be intermixed with polyurethane polymer and anticoagulant such as heparin added to reduce the possibility of further coagulation (abstract, column 2, lines 37 and 45; column 4, lines 53-63); the coating composition can also contain drugs such as anti-inflammatory agent, anti-oxidants and nitric oxide releasing agent (column 6, lines 14-31) (abstract).

Dinh discloses the coated medical device of the instant claims but is silent on the trend of the concentration of the active agents, that is, the prior art fails to disclose whether the active agent is inwardly decreasing or increasing. The comprising allows for the presence of fibrin in the coating composition. However, there is no demonstration in applicants' specification showing that an inwardly decreasing concentration of the active agent provides unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made coat a medical device with the coating composition of Dinh for treating or inhibiting restenosis. One having ordinary skill in the art would have been motivated to include appropriate amounts of the active agent in the coating composition for an effective delivery for effective measured inhibition or treatment.

Loeffler (US 5,897,911) discloses a polymer-coated stent for treating restenosis and the coating composition comprises polyurethane, nitric oxide and heparin (abstract, column 1, line 53; column 2, lines 4, 5, 56 and 57; and column 3, lines 1-35). Loeffler does not disclose the

decreasing or increasing nature of the concentration gradient of the active agent. Loeffler and Dinh are or equivalent significance to the instant claims.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 16-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, and 18-38 of U.S. Patent Nos. 6,379,691 and 6,218,016 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined coated device and the issued claims have same utility in treating or inhibiting restenosis with compositions that contain polymeric network and active agents such as heparin and nitric oxide.

7. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after


Art Unit: 1615


the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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